



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 17 2007

Re: Prezista
Docket No.: 2006E-0502

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,248,775, filed by G.D. Searle & Co., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Prezista (darunavir ethanolate), the human drug product claimed by the patent.

The total length of the regulatory review period for Prezista (darunavir ethanolate) is 1,253 days. Of this time, 1,070 days occurred during the testing phase and 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 19, 2003.

The applicant claims January 20, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 19, 2003, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 23, 2005.

FDA has verified the applicant's claim that the new drug application (NDA) for Prezista (darunavir ethanolate) (NDA 21-976) was initially submitted on December 23, 2005.

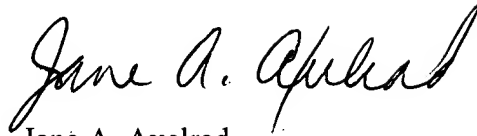
3. The date the application was approved: June 23, 2006.

FDA has verified the applicant's claim that NDA 21-976 was approved on June 23, 2006.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jane A. Axelrad". The signature is fluid and cursive, with the first name "Jane" being the most prominent.

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Phillip Johnson, Esq.
Johnson & Johnson
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